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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/479,995	06/07/1995	ROBERT G. PERGOLIZZI	ENZ-(D1)(C2)	8797
28171	7590	02/17/2004	EXAMINER	
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/479,995	PERGOLIZZI ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/28/03, 8/4/03, & 10/27/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 283-362, 364-380, 382-398, 400-404, 406-439 and 441-547 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 508 and 511 is/are allowed.
- 6) ☒ Claim(s) 283-362, 364-380, 382-398, 400-404, 406-439, 441-506, 509, 510, 512-527 and 532-547 is/are rejected.
- 7) ☒ Claim(s) 507 and 528-531 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

It is acknowledged that the previously sent Notices of Suspension have expired while multiple counts and multiple party Interference issues have been considered but are presently not appropriate to proceed at this time due to a lack of at least one claim which is indicated as allowable which corresponds to any of the proposed counts. The submission of multiple requests for Interference is however acknowledged.

It is also acknowledged that numerous additional claims have been submitted for examination. The instant application has been fully reconsidered due to these new issues present in the presently pending claim set which has raised new issues as set forth below.

Applicants' arguments, filed 3/28/03, 8/4/03, and 10/27/03, have been fully considered and the following rejections and/or objections newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 512-521, 523, 524, and 526 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that newly added claims 506-531 have been pointed to by applicants to originally filed claims for written support. Newly added claims 506-531 have been pointed to originally filed claims 72-93 and 96-99, respectively. Several inconsistencies,

however, are present which supports this NEW MATTER rejection due to respective claims as listed above not supplying written basis for the now pending claims.

In newly added claim 512 the last line thereof is not the same as the last line of claim 78 which was pointed to for support. In particular original claim 78 is directed to a DNA molecule which is carrying a polynucleotide which comprises sequence options as listed therein. The apparently corresponding now pending claim 512 now also is directed to such a polynucleotide but now also includes an option which is an unspecified "sequence" as well as alternatively including a further subdivision of the polynucleotide to include a segment which is of low complexity. This undefined "sequence" option for claim 512 is NEW MATTER as well as the further subdivision of the polynucleotide to contain a "segment" which subdivision was not previously cited in the pointed to claim 78. Claim 524 also contains this NEW MATTER in corresponding inconsistently from original claim 90. Claims which depend directly or indirectly from claims 512 or 524 also contain this NEW MATTER due to their dependency.

Claim 513 also further contains NEW MATTER in that it cites a filamentous phage which "contains" a DNA molecule whereas in contrast originally filed claim 79 discloses that the DNA molecule "is" the filamentous phage. The added "contains" vs. "is" different is NEW MATTER in newly added claim 513. This is NEW MATTER in claim 514 which depends from claim 513. This same NEW MATTER is present in claim 520 which is not consistent with the pointed to originally filed claim 86. Claim 521 also contains this NEW MATTER due to its dependence from claim 520. This NEW

MATTER issue is also present in claim 523 which is not consistent with the pointed to originally filed claim 89.

**VAGUENESS AND INDEFINITENESS as well as
NEW MATTER**

Claims 283-362, 364-380, 382-398, 400-404, 406-439, 441-505, and 532-547 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed compositions, kits, and methods, cite a signaling entity nucleic acid portion per se therein which is capable of either binding or hybridizing with the bridging entity nucleic acid second portion. See, for example, claim 283, lines 7-8, specifically. These binding "or" hybridizing" options are not commensurate in scope with the interaction cited for said signaling entity with the bridging second portion which only cites annealing and not generic binding practice. This is directly cited in the specification on page 17, last 4 lines, wherein this annealing practice is cited but no generic binding between the above two cited entities. This limited citation to annealing is also present in originally filed instant claim 1.

This above discussed limitation to annealing as originally filed, which is reasonably interpreted as functionally equivalent to hybridizing, whereas, in contrast, the present claims are broader to include generic binding also supports the below NEW MATTER rejection of the presently pending instant claims.

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Claims 283-362, 364-380, 382-398, 400-404, 406-439, 441-505, and 532-547 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The NEW MATTER has been described in the immediately preceding paragraph.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 509, 510, 512-517, and 520-527 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by MOLECULAR CLONING [Maniatis et al. (1982)].

Pages 51-54 of Maniatis et al. disclose various filamentous phages which contain DNA molecules as well as both single and double stranded nucleic acid forms thereof which anticipates the above instant claims. Sequences therein are disclosed on page 53 which specifically read on sequences as cited in instant claim 512, for example.

Such polynucleotides may also be interpreted reasonably as functional segments therein which also comprise a polysaccharide as required in instant claim 509. It is well known that each nucleotide residue is a saccharide unit as in said claim 509. Page 53 of Maniatis et al. also discloses segments of the M13 DNA which are receptors for

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restriction endonuclease binding sites as also required in instant claim 510. Page 52 of the reference cites the presence of a covalently attached polylinker segment which produces a detectable signal via insertions therein thus anticipating instant claims 522 etc.

Claims 506, 509, and 510 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Langer et al. [PNAS 78(11) 6633 (1981)].

Langer et al. discloses polynucleotides of DNA or RNA with biotin covalently attached which covalent attachment also results in antibody attachment which anticipates the above listed instant claims. Such an antibody is also a receptor for biotin binding as required in certain instant claims such as claim 510. See the entire document and especially page 6635, first column, second full paragraph.

CLAIM OBJECTIONS

Claims 507 and 528-531 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 508 and 511 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

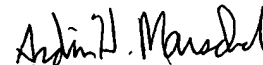
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 9, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER